

## **REMARKS**

Reconsideration of the subject application in view of the following remarks is respectfully requested. Claims 11-20, 22, 23, 26-28 and 41-56 have been cancelled. New method claims 57-86 have been added to particularly point out Applicant's invention with specificity, among other things. New claims 58-86 depend on claim 57, and correspond with the dependent claims previously submitted. No new matter has been added by this amendment. Applicant reserves the right to pursue any subject matter cancelled by way of this amendment in a division or continuation application, without prejudice.

### **The Rejections Asserted in the Office Action**

In the outstanding Office Action, Claims 11-20, 22, 23, 26-28 and 41-56 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Pat. No. 5,906,830 to Farinas et al ("Farinas").

### **Response by Applicant**

Applicant respectfully traverses the Examiner's rejections primarily because of the reasons set forth herein below.

Applicant contends the Examiner has not satisfied the burden necessary for establishing a *prima facie* case of obviousness, as alleged in the outstanding office action.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

- combine reference teachings. Second, there must be a reasonable expectation of success.

Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Farinas discloses a method of using heat to create supersaturation. In contrast, the present independent claim is directed to a method which involves "conducting chemical operations on the composition over a period of time, wherein the chemical operations result in the formation of a liquid or solid non-crystalline carrier matrix," among other things. The carrier matrix, as claimed, includes a "first property that the biologically active agent can be dispersed or dissolved therein up to a second degree of saturation," wherein this "second degree of saturation" is "greater than the first degree of saturation." Furthermore, the carrier matrix imparts a "second property that substantially inhibits precipitation of the biologically active agent after saturation of the biologically active agent in the composition," among other things. As now claimed, the biologically active agent is "added to the composition during the period of time for conducting the chemical operations" in an "amount that saturates the carrier starting substance and carrier matrix therein" in accordance with "the first and second degrees of saturation to form the biologically active composition."

Applicant respectfully disagrees with the Examiner's contention that the presently claimed method is disclosed or suggested by Farinas, or that Farinas would motivate one of ordinary skill in the art to conduct the method now claimed to one of ordinary skill in the art. The Examiner states that although "Farinas does not specifically teach a chemical process," as now claimed by Applicant, "heating a reaction has the potential of eliciting a chemical reaction and this knowledge is within the purview of one of ordinary skill in the art." (See Page 3 of the outstanding Office Action). This is presumed to be the Examiner's statement of motivation.

Applicant contends that Farinas, in using heat to create supersaturation, does not provide sufficient technical support for establishing *prima facie* obviousness of the claims as amended herein. For example, heating of the reaction because it has the potential of eliciting a chemical reaction does not anticipate a method as now claimed including, "supplying a composition including a carrier starting substance having a property that the biologically active agent can be either dispersed or dissolved therein up to a first degree of saturation," "conducting chemical operations on the composition over a period of time, wherein the chemical operations result in the formation of a liquid or solid non-crystalline carrier matrix, the carrier matrix having a first property that the biologically active agent can be dispersed or dissolved therein up to a second degree of saturation, the second degree of saturation being greater than the first degree of saturation and a second property that substantially inhibits precipitation of the biologically active agent after saturation of the biologically active agent in the composition," and "adding the biologically active agent to the composition during the period of time for conducting the chemical operations in an amount that saturates the carrier starting substance and carrier matrix therein according to the first and second degrees of saturation to form the biologically active composition."

Applicant's position is supported by case law, since it has been held that not only must there be some reasonable expectation of success in the references themselves to support a §103 rejection, but the prior art or surrounding circumstances must render the Applicant's claimed invention obvious to do rather than obvious to try. *In re Tomlinson*, 150 USPQ 623 (CCPA 1966). At most, Farinas might lead one of ordinary skill in the art to heat various compositions, but even so, this differs from Applicant's invention, as discussed above, and merely heating compositions could not possibly yield the reasonable expectation of success as required for

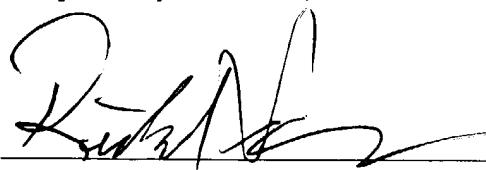
maintaining a §103 rejection. Clearly, Applicant's invention as now claimed is not rendered obvious by Farinas.

Thus, Applicant respectfully submits that since independent claim 57 contains limitations which are neither taught nor suggested by Farinas, either alone or combined with any other reference, this claim is allowable. Furthermore, since the claims that depend from independent claim 57 provide further limitations thereto, the dependent claims are also not rendered obvious by Farinas, either alone or combined with any other reference. Accordingly, it is submitted that Claims 57-86, as now claimed, distinguish the subject invention from Farinas, and withdrawal of the rejection is therefore respectfully requested.

In conclusion, it is respectfully submitted that as a result of this amendment and discussion relating thereto, all of the claims presently pending in this application are in condition for allowance, and such action is earnestly solicited.

If the Examiner believes that a personal or telephonic interview may facilitate resolution of any remaining matters, Applicant's representative may be contacted at the number indicated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Richard H. Newman', is written over a horizontal line.

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